

CHOLINESTERASE MONITORING FOR AGRICULTURAL PESTICIDE HANDLERS

GUIDELINES FOR HEALTH CARE PROVIDERS IN WASHINGTON STATE

John Furman, Occupational Nurse Consultant

Department of Labor & Industries

WISHA Policy & Technical Services

January 2006

Modeled on the California “*Guidelines for Physicians who Supervise Workers Exposed to Cholinesterase-Inhibiting Pesticides.*” Portions used with permission from: Robert Schlag, M.Sc., Chief Pesticide Epidemiology Unit Office of Environmental Health Hazard Assessment; 1001 I Street, 12th Floor; Sacramento, CA 95814

Contributors: Patricia Boiko, MD, MPH; Matthew Keifer MD, MPH; Karl Weyrauch MD, MPH;
Cheryl Hanks, RN

Contents

2006 program highlights	3
Resources	4
Rule overview	5
Responsibilities	6
Medical Monitoring Flow Chart	7
Cholinesterase inhibition	8
Cholinesterase monitoring	9
Conducting a monitoring program	10
Department of Health Pesticide Program	13
Treating and reporting pesticide illness	14
Confidentiality	15
Appendix A: Frequently asked questions	16
Appendix B. Sample Recommendation form	22
Appendix C: Sample Informed Consent	23
Appendix D: Sample medical monitor agreement form	25
Appendix E: Sample initiation of medical monitoring form	26
Appendix F: Sample employee no longer requires monitoring form	27
Appendix G: Cholinesterase monitoring information	28
Appendix H: Laboratory requisition slip	29
Appendix I: Specimen collection and shipping instructions	30
Appendix J: Handling hours report form	31
Appendix K: Chapter 296-307-148 WAC Cholinesterase Monitoring	32

PROGRAM HIGHLIGHTS FOR 2006

1. The Cholinesterase Monitoring rule has been updated with an effective date of February 1, 2006.
2. The Washington State Public Health Laboratory (PHL) will remain the only approved laboratory through 2006. All cholinesterase tests done under the program must be submitted to the PHL.
3. All testing costs will continue to be absorbed by L&I. However employer cost reimbursements for clinic service and program administration costs will no longer be available.
4. The exposure threshold requiring cholinesterase monitoring will remain as handling toxicity category I or II organophosphate or N-methyl-carbamate pesticides for 30 or more hours in any consecutive 30 day period.
5. The employer will continue to submit the L&I Cholinesterase Handling Hours form (F413-065-000) for each periodic/follow-up test and a copy of this form must be submitted to the PHL with each test requisition slip.
6. The employer is required to obtain a written recommendation from the medical provider for each employee test (incl. baselines) and evaluation. The employer is then required to provide a copy of the written recommendation to the employee within 5 days of the employer receiving the written recommendation. The employer has the option of either providing a copy to the employee directly or contracting with the medical provider to provide a copy to the employee.
7. Because the employer does not need specific test results to take actions required under rule these results are considered personal medical information under RCW 70.02. The medical provider should only include the percent change from baseline with the written recommendations unless the employee has given written authorization to share test results with the employer.
8. L&I will no longer be routinely conducting research investigations in response to significant cholinesterase depression. The primary reason for conducting these visits was to gather data during the 2004/05 rule evaluation period. Beginning in 2006 the rule will be supported through L&I's consultation and compliance programs. However, random compliance and data gathering workplace visits may be conducted.

RESOURCES

This manual is written to help health care providers understand their responsibilities under the Cholinesterase Monitoring rule and to become active participants in the program. It presents background information, practical suggestions, and tools to help facilitate participation. Additional resources are listed below:

Cholinesterase monitoring clinical consultation services:

- John Furman, ONC WISHA Services (360) 902-5666
- Dr. Matthew Keifer, Departments of Medicine and Environmental Health, University of Washington (206) 616-1452
- 24 hour support through the University of Washington Occupational Medicine Residency Program (206) 341-4446

Laboratory Services

- Harold Ruarke or Marina Silverstone, Washington State Public Health Laboratory (206) 418-5400

List of Class I & II organophosphate and N-methyl-carbamate pesticides

- WSDA Pesticide Web Page
<http://agr.wa.gov/PestFert/Pesticides/WorkerProtection.htm>

Pesticide Illness reporting information

- DOH Pesticide Program 1-888-586-9427

Web resources:

- For health care providers
<http://www.lni.wa.gov/Safety/Topics/AtoZ/Cholinesterase/Providers.asp>
- For employers and employees
<http://www.lni.wa.gov/Safety/Topics/AtoZ/Cholinesterase/default.asp>

RULE OVERVIEW

1. The employer is required to keep records of all employee handling of covered pesticides, and retain those records for seven years, even if employees decline to participate in testing.
2. Cholinesterase monitoring (RBC and serum cholinesterase) is provided to employees who handle covered pesticides for 30 or more hours in any consecutive 30-day period
3. Employers will be required to ensure that employees eligible for medical monitoring will receive training that includes at a minimum:
 - The human health hazards associated with exposure to cholinesterase-inhibiting pesticides
 - The purpose and requirements of cholinesterase monitoring.
4. Employers will identify a medical provider to provide (at no cost to the employee, and at a reasonable time and place) baseline and periodic testing, interpretation of test results, and recommendations resulting from those test results
5. Employees may choose to decline cholinesterase testing only after receiving training and consulting with the medical provider. Employees who decline participation must be provided with a copy of their signed and witnessed declination form.
6. Pre-exposure baseline testing will be conducted annually.
7. Employers whose employees who handle only N-methyl-carbamate pesticides will be exempt from the requirement to offer those employees cholinesterase testing.
8. Hours spent mixing and loading using closed systems (as described in WAC 296-307-13045(4)(d)) will not be counted as exposure hours for the purposes of periodic monitoring beyond the baseline, although time applying pesticides using these systems will be counted.
9. Periodic testing will be required within 3 days of meeting the designated exposure thresholds *or* at least every 30 days while exposure is expected to exceed thresholds.
10. Cholinesterase depressions will require the following employer actions:
 - A depression of 20% or more from the employee's personal baseline will require the employer to assess possible routes of exposure by conducting a work practice investigation.
 - An RBC cholinesterase depression of 30% or more from the personal baseline or a serum cholinesterase depression of 40% or more from the personal baseline will require the employee to be temporarily removed from organophosphate and N-methyl-carbamate exposure and the employer to conduct a work practice investigation.
 - An employee removed from exposure will not be allowed to return to handling covered pesticides or to participating in other exposure-prone activities until his or her cholinesterase levels are within 20 percent of the personal baseline.
11. Medical removal protection until return to normal duties (not to exceed 3 months) will be made available to employees removed from handling due to cholinesterase depression.
12. The employer must maintain (or contract with the provider to maintain) monitoring and related medical Records for 7 years. **5**

Responsibilities

Employers must:

- Implement a monitoring program for employees who, as part of their job duties, handle toxicity Categories I or II OP or N-methyl-carbamate pesticides with the signal words, “Danger” or “Warning” on the label.
- Follow all occupational health recommendations from the clinician.
- Provide employee training on the health hazard of cholinesterase-inhibiting pesticides and the purpose and requirements for medical monitoring.
- Provide Pesticide Handling Hours reports to clinicians for each employee test
- Make sure copies of employee test results and clinician written recommendations are maintained for seven years.

Clinicians must:

- Discuss the risks and benefits of participation in the cholinesterase-testing program with the employee.
- Obtain employee signed consent or declination for program participation.
- Provide and interpret baseline and periodic testing of blood cholinesterase levels.
- Notify worker of test results and recommendations
- Provide written occupational health recommendations as indicated in the rule
- Perform an initial intake exam, including a medical history (recommended.)
- Assess other conditions that may affect the patient’s cholinesterase levels
- Monitor employee for cholinesterase recovery and return to handling duties

Department of Health Public Health Laboratory Assess adequacy of sample upon receipt and notify provider if sample not adequate.

- Determine levels of serum and RBC ChE following the standard operating procedures.
- Mail results to provider.
- Compile data and transmit electronically to CMDS.

Department of Health Non-Infectious Conditions Epidemiology

- Developed the Cholinesterase Monitoring Data System (CMDS.)
- Maintains CMDS.
 - Manually link follow-ups to baselines that are not matched automatically.
 - Notify L&I of depressions requiring action.

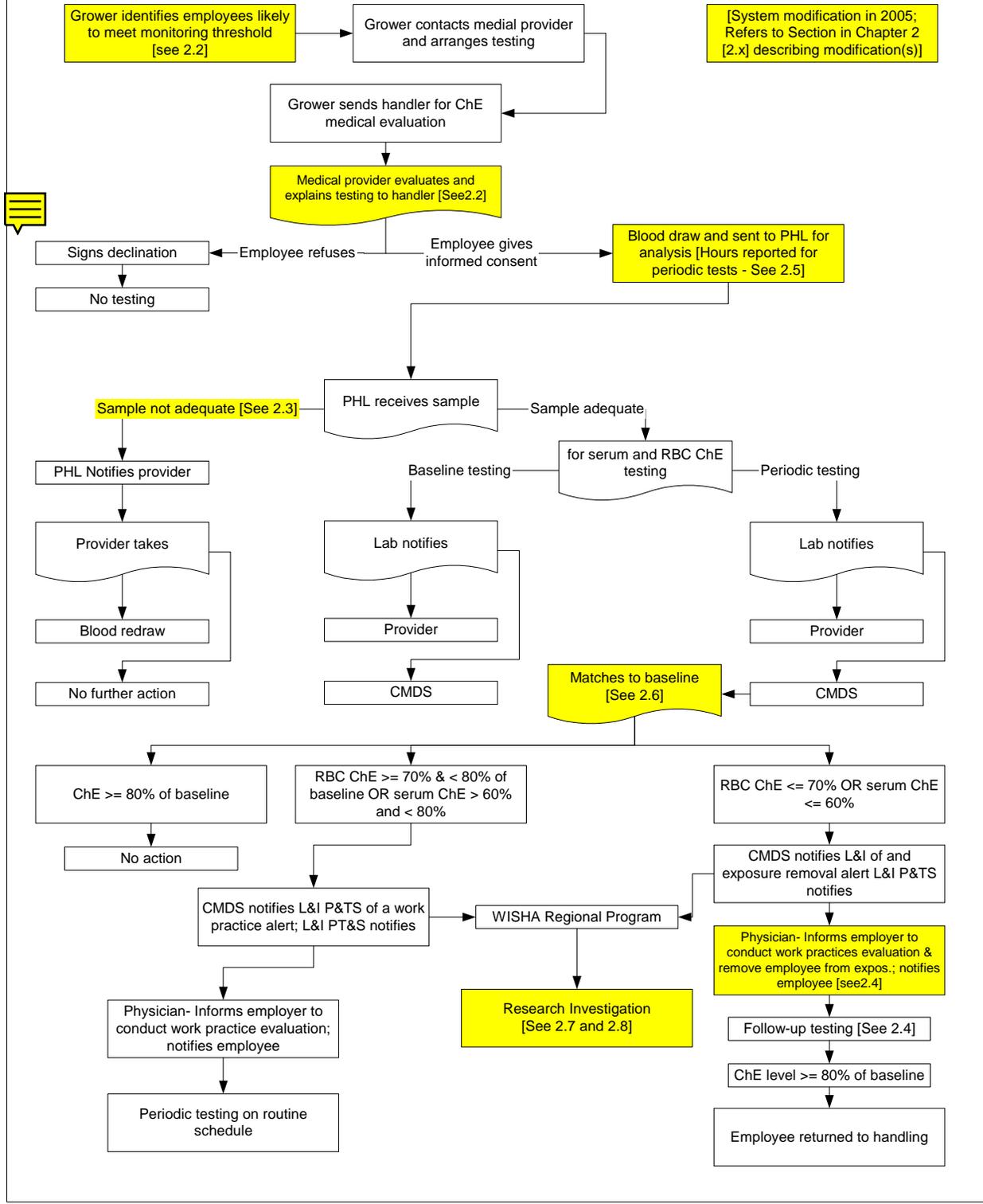
L&I must implement and evaluate the rule, including:

- Collecting data.
- Reviewing stakeholder input.
- Distributing provider guidelines.
- Modifying the rule as appropriate.

Employees must be:

- Informed about the Rule and its requirements.
- Instructed in the health hazards of OP and N-methyl-carbamate pesticides.
- Given the chance to freely and willingly consent or decline to participate in the program.

Figure 1: 2005 ChE monitoring system review



CHOLINESTERASE INHIBITION

What is cholinesterase?

Cholinesterase (ChE) is the general term for two enzymes in the human body: acetylcholinesterase (AChE) and butyrylcholinesterase or serum cholinesterase (PChE). AChE can also be found in the blood as red blood cell cholinesterase. In the nervous system AChE acts to “turn off” the signal delivered by cholinergic nerves by removing the neurotransmitter acetylcholine. Thus if AChE is inhibited, acetylcholine builds up causing over-stimulation of cholinergic systems. This over-stimulation of muscles, glands and other nerves is what causes most of the symptoms associated with overexposure to cholinesterase-inhibiting pesticides.

Blood test measurements of both AChE and PChE can be used as surrogate measures of nervous system AChE activity. Because cholinesterase levels vary greatly between individuals (inter-individual variability) it is necessary to establish a pre-exposure baseline functioning level for each individual in order to determine meaningful change in cholinesterase levels. The cholinesterase monitoring rule requires that individual baseline levels be determined on an annual basis.

Which pesticides are cholinesterase inhibitors?

Organophosphate (OP) and N-methyl carbamate pesticides are insecticides, which cause toxicity both in the pest and in non-pest species (such as humans) by inhibiting AChE. OP and N-methyl-carbamates inhibit cholinesterase by binding to the active site of the enzyme. OPs may bind irreversibly with the enzyme while the N-methyl-carbamate bond is reversible. OP and N-methyl-carbamates are among the most toxic substances produced by modern chemical technology. Aldicarb (an N-methyl- carbamate still widely used) for example has an oral LD50 (lethal to 50% of test animals) of 1 mg per kilogram.

How do overexposures occur?

Overexposure to these pesticides can occur through a variety of means including:

- Most commonly skin or eye contact with spray while applying or with concentrate while mixing
- Absorption across the lungs if inhaled while spraying.
- Ingestion although rare may be a route of exposure.

What are the symptoms of cholinergic illness?

Generally symptoms of cholinergic illness do not appear until cholinesterase depression exceeds 50% from an individual’s baseline. However, mild symptoms may occur without obvious cholinesterase depression. Signs and symptoms of cholinesterase illness include the following

- Mild cases: Tiredness , weakness, dizziness, nausea, headache, and blurred vision;
- Moderate cases: sweating, tearing, drooling, vomiting, tunnel vision, and twitching;
- Severe cases: abdominal cramps, excess urination, tremors, staggering gait, pinpoint pupils, hypotension, slow heartbeat, breathing difficulty.

CHOLINESTERASE MONITORING

What does the cholinesterase test measure?

Cholinesterase activity in the blood acts as a convenient biomarker that reflects the activity of acetylcholinesterase in the nervous system. By periodically comparing measurements of cholinesterase activity to a subject's established baseline (prior to pesticide exposure), episodes of overexposure can be identified before the occurrence of clinical illness. An appropriate testing schedule is intended to detect overexposure before the occurrence of clinical illness.

*Note: The Department of Health laboratory requests **serum** to measure PChE; when possible specimens should be clotted, spun down, and serum drawn off for shipping (see Appendix J: Instructions for Collecting and Shipping Blood Specimens)*

Serum and RBC Cholinesterase

Both serum (or plasma) and RBC cholinesterase must be determined on each sample tested because the two tests have different meanings and the results need to be considered in combination for proper interpretation. Certain organophosphates exhibit preferential inhibition of either serum or RBC cholinesterase activity.

Serum cholinesterase is more labile than RBC cholinesterase and is generally inactivated more rapidly after exposure to organophosphates, but it may also be depressed by other factors such as heavy alcohol intake, infection, and hepatic disease. Since serum cholinesterase is produced in the liver, it can be regenerated relatively quickly. After mild overexposure there is sometimes a rebound phenomenon resulting in slightly elevated levels.

RBC cholinesterase is the same enzyme as the AChE in the nervous system. It is considered a more accurate measure of the actual nervous system AChE activity. This enzyme is often depressed more slowly than serum cholinesterase by exposure to organophosphates. Regeneration of RBC cholinesterase is slower and is generally measured at the rate that new red blood cells are produced, slightly less than 1% per day.

Why must baseline levels be established?

It is essential to establish an individual's baseline value for both serum and RBC cholinesterase activity in order to interpret subsequent results. Since there is a fourfold difference between the upper and lower limits of a laboratory "normal population range," the normal range cannot be relied upon for exposure monitoring. Baseline determinations must be established at least 30 days since the employee last handled organophosphate or N-methyl-carbamate pesticides. The rule allows for a "working baseline" to be obtained for employees who initially decline testing but later choose to participate.

Use of approved laboratories

A laboratory performing cholinesterase tests as part of medical supervision must be approved by L&I and shall have a quality control program and an analytical method acceptable to that department. Through 2006, only the Washington State Department of Health Public Health Laboratory (DOH-PHL) is approved by L&I.

Note: All routine monitoring tests must be done through the DOH-PHL. However, DOH-PHL services are only available during normal business hours. If a situation occurs where ChE test turn around is required in fewer than five days (e.g., medical management of an acute, symptomatic exposure) the normal channels for laboratory testing used by your clinic should be followed. Subsequent ChE tests to monitor recuperation may be submitted to the DOH-PHL.

CONDUCTING A MONITORING PROGRAM

Which employees must be monitored?

Agricultural employees who handle toxicity category I or II organophosphate or N-methyl-carbamate pesticides for 30 or more hours in any consecutive 30-day period are covered under the medical monitoring requirements of the rule. Pesticide handling activities include, but are not limited to loading, mixing or applying pesticides, maintenance or cleaning of contaminated equipment or assisting in such activities (see the definition of handling in WAC 296-307-11005).

What do I do at the first visit?

- You **must** provide information on the risks and benefits of cholinesterase monitoring and obtain written authorization for testing or declination.
- Baseline blood samples may be obtained at this time if the employee has not handled OP or N-methyl-carbamate pesticides in the last 30 days
- Taking a pre-exposure medical history is recommended including pertinent identifying, occupational and medical information is recommended.

Note: Due to the lability of the carbamate/cholinesterase bond baseline and periodic testing is not required for employees whose sole exposure is limited to handling N-methyl-carbamate pesticides only.

What other medical conditions need to be evaluated?

The clinician should also inquire about a history of conditions that, may be adversely affected by cholinergic reactions, such as significant respiratory, hepatic, or cardiovascular disease,

Other conditions in which complications may be anticipated include peptic ulcer, anemia, degenerative diseases of the central nervous system, chronic colitis, history or evidence of psychosis, and diseases such as myasthenia gravis and glaucoma, which are treated with cholinesterase inhibitors. About 1-3% of the population has congenitally low serum cholinesterase levels. This deficiency may increase the direct effect of inhibitors on the nervous system AChE.

What is the schedule for periodic testing?

Periodic tests are required whenever an employee meets or exceeds the 30 hour exposure threshold but no more often than every 30 days. The clinician may recommend more frequent testing based on factors such as medical risks, handling activities, frequency of exposure, and toxicity of pesticides handled.

How do I interpret periodic test results?

The frequency of periodic follow-up cholinesterase tests is primarily a medical decision although the rule requires minimum intervals (see Rule Section 296-307-14810). Factors to consider are workplace conditions, pesticide toxicity, duration of exposure, and employee hygiene

First, the clinician needs to calculate the percentage change from baseline. The calculation should be done separately for RBC cholinesterase and serum cholinesterase. Mathematically, the percentage change from baseline is $((X - Y)/X) * 100$, where X is the baseline value, and Y is the follow-up value. The ChE rule uses percent inhibition (e.g., “20% below baseline”). For example if RBC baseline = 14.4 and periodic test = 9.8 then $((14.4 - 9.8) / 14.4) * 100 = 31.94\%$ depression from baseline

Next, the clinician needs to review the differential diagnosis, in order to determine whether a pre-existing condition, unrelated to pesticide exposure, may be causing an abnormal cholinesterase value, as described above.

What happens if the cholinesterase level is depressed?

Cholinesterase limits have been set at levels that indicate overexposure. These limits allow an adequate margin of safety; i.e., set at levels not likely to be associated with symptomatic illness. Washington State regulations are outlined in the following table.

Table 1 - Required Responses to an Employee’s Depressed Cholinesterase Levels

When:	Action to be taken:	Methods:
An employee’s RBC or serum cholinesterase levels fall more than 20% below the baseline	Evaluate the employee’s workplace and work practices to identify and correct potential sources of pesticide exposure	Review with the employee: <ul style="list-style-type: none"> • Personal protective equipment (PPE) and its condition • Employees’ PPE usage • General sanitation and decontamination practices and availability of decontamination facilities required by WAC 296-307-13050 • Pesticide handling practices • Pesticide label requirements
An employee’s RBC cholinesterase level falls 30% or more from the baseline. OR An employee’s serum cholinesterase level falls 40% or more from the baseline	Remove the employee from handling and other work exposures to organophosphate and N-methyl-carbamate pesticides such as thinning and harvesting in recently treated areas AND Evaluate the employee’s work practices to identify and correct potential sources of pesticide exposure	<ul style="list-style-type: none"> • When available; provide the employee with other duties that don’t include handling and other work exposures to organophosphate and N-methyl-carbamate pesticides • Provide medical monitoring and cholinesterase testing as recommended by the clinician • Provide salary and benefits as if employee was continuing pesticide application activities
A removed employee’s cholinesterase levels return to 20% or less below baseline	The employee may return to handling class I and II organophosphate and N-methyl-carbamate pesticides	Continue periodic cholinesterase monitoring

Table 1. The rule requires the employer to investigate work practices, including a review of the safety equipment used and its condition, employee sanitation, pesticide handling procedures, and equipment usage, whenever an employee’s cholinesterase, either serum or RBC, falls below 80% of baseline. The employer is then required to maintain a written record of the findings, any changes in equipment or procedures, and any recommendations made to the employee.

What happens if the employee is temporarily removed from exposure?

The employer should assign an employee to other duties while temporarily removed from exposure to cholinesterase-inhibiting pesticides. The rule requires the employer to provide medical removal protection benefits for a maximum of three months on each occasion that an employee is temporarily removed from exposure, whether assigned to other duties or removed from work. Removal benefits include maintenance of the same pay, seniority, and other employment rights and benefits of an employee as though the employee had not been removed.

- Removal from exposure means restriction from any handling activities as defined in WAC 296-307-11005, avoidance of areas where OP or N-methyl carbamate materials are handled or mixed and avoidance of any contact with opened containers or with equipment that is used for mixing, dusting, spraying, or otherwise applying pesticides. This restriction includes cleaning or repair of mixing or application equipment. In addition to handling activities, the removed employee should be kept from exposure to OP and N-methyl carbamate residues.
- When employees have been removed from exposure because their cholinesterase activity has fallen below the acceptable limits, the worker should not be returned to handling cholinesterase-inhibiting pesticides until enzyme activity levels have returned to within 20% of the baseline value for both serum and RBC cholinesterase.
- The employer is required to maintain, for seven years, written records of the dates of removal and the dates when the employee returned to handling OP and N-methyl-carbamate pesticides.

What is the schedule for conducting follow-up tests to monitor cholinesterase recovery?

Serum cholinesterase is regenerated quickly in the liver. Follow-up testing to monitor recovery after a depression $\geq 40\%$ from baseline can be conducted immediately and then as often as on a weekly basis until the level returns to within 20% of baseline.

RBC cholinesterase is generated with RBC's in the bone marrow. RBC's are replaced at a rate of about 1% per day. When scheduling follow-up tests to monitor recovery after a depression of $\geq 30\%$ from baseline the clinician can use the 1% recovery rate as a ruler. For example, for an RBC cholinesterase depression of 45% from baseline it can be expected that regeneration to within from baseline will take about 25 days. However, the clinician may want to test immediately after receiving a result indicating depression $\geq 30\%$ from baseline in order to verify the result and set a schedule for follow-up testing based on the employee's most current cholinesterase level.

What is my responsibility to communicate evaluation results and medical recommendations?

The rule requires that the employer obtain a written recommendation from the health care provider for each employee test (incl. baseline) and evaluation. The employer must ensure that the employee receives a copy of the recommendation within 5 days after the employer receives it. The employer may chose to provide a copy directly to the employee or contract with the health care provider to provide a copy to the employee.

Unless the employee has given written consent to share specific test results with the employer the written recommendation should only include the percent change in both serum and RBC cholinesterase. As the employer, only needs percent change from baseline, to take the actions required by rule and does not need specific test results, the specific test results and any other personal medical information can only be shared with written employee consent per RCW 70.02.

DOH PESTICIDE PROGRAM

What is my responsibility to report pesticide illness and poisoning?

Surveillance and reporting are essential to:

- Identify high-risk pesticides and use practices.
- Target intervention and prevention activities.
- Provide education and support for physicians and other health care providers. Pesticide-related illness is a reportable condition to the Washington State Department of Health (DOH) per WAC 246-10. All types of pesticide-related cases must be reported, including skin and eye injuries, systemic poisonings, suicides and homicides, and home and occupational exposures. A case seen as pesticide poisoning or as a condition suspected as pesticide-related may not be categorized as a "first-aid case" and must be reported.

The legal requirements, or Notifiable Conditions, for disease reporting are the foundation for disease surveillance and are listed in Table 2.

Table 2: Washington State Surveillance and reporting requirements

REPORTING REQUIREMENTS	Health care providers	Hospitals	Laboratories	Local health jurisdictions
HOSPITALIZED, FATAL, OR CLUSTER	Immediately notifiable to DOH Pesticide Program	Immediately notifiable to DOH Pesticide Program	No requirements for reporting	No requirements for reporting
OTHER	Notifiable <u>within three work days</u> to the DOH Pesticide Program	No requirements for reporting	No requirements for reporting	Educate health care providers regarding reporting requirements to the state
Telephone	800-222-1222 (Poison Center, by agreement for 24 hour access) <u>or</u> 888-586-9427 (DOH Monday-Friday 8:00am-5:00pm)			
Online	http://www.doh.wa.gov/notify/nc/pesticide.htm			

Washington is one of eight states that actively tracks and investigates pesticide-related illnesses and is second only to California in the number of cases of pesticide poisoning investigated annually. From 1995 through 1999 the DOH investigated 1,163 cases of pesticides illness in the agricultural environment and 1,080 cases in the non-agricultural environment. Approximately 40% of all identified cases occurred among employees in agricultural settings.

Information about the DOH Pesticide Program can be found at www.doh.wa.gov/ehp/ts/Pest.htm

Tools for measuring pesticide exposure

Pesticide Exposure Interview Questions (adult and pediatric) can be found at

www.doh.wa.gov/notify/other/pestinter.htm or

www.doh.wa.gov/notify/other/pestinter.pdf

Poisoning data and information about the DOH Pesticide Program can be found at www.doh.wa.gov/ehp/ts/Pest.htm

TREATING AND REPORTING PESTICIDE ILLNESS

A plan for emergency care and transfer to an appropriate facility should be established. Staff should be trained to recognize symptoms of pesticide poisoning and be familiar with the facility's pesticide poisoning emergency management plan. The most important medications for treatment of toxicity from cholinesterase inhibition include atropine and pralidoxime and should be present at emergency treatment sites. An excellent reference concerning the treatment of pesticide poisonings is the Environmental Protection Agency (EPA) publication Recognition and Management of Pesticide Poisonings. This is available free from the EPA. Order a printed version or download it at <http://www.epa.gov/oppfod01/safety/healthcare/handbook/handbook.htm>. (Available in both English and Spanish)

Cholinesterase tests should be repeated any time employees become sick while working with cholinesterase-inhibiting agents or develops symptoms within 12 hours of their last exposure. **Any suspected pesticide-related illness is a reportable condition and should be reported to DOH (1-360-236-3361 or 1-888-586-9427)**. If a worker dies within 24 hours of their last exposure to organophosphates, the clinician should attempt to arrange for a post-mortem cholinesterase test.

Related principles of occupational medicine

Mutual understanding between employers and clinicians

Employers are responsible for obtaining and paying for required medical monitoring. It is important that both clinicians and employers clearly understand their relationship and respective responsibilities. Employers may wish to engage medical services for a complete industrial medical program or they may wish to provide only the basic occupational health services required by state regulations.

Employers' expenses for a medical monitoring program are part of the "cost of production" for enterprises using hazardous materials. Agreement about services and costs are best arrived at through personal discussion. Clinicians may find it advisable to set their fees according to the amount of time and effort they estimate this monitoring will take rather than to charge solely on the basis of each patient visit or examination. Much of the work will be preventive, such as ordering and interpreting cholinesterase tests, and may not involve actual patient visits or examinations.

Occupational Health services

In their occupational health role, clinicians' responsibilities go beyond the familiar therapeutic doctor-patient relationship to include preventive and consultative functions for the individual workers and for employers' work forces as a group. These functions include the following:

- Clinicians should endeavor to be conversant with the work practices and exposures of the workers that they medically supervise. For this purpose it is good practice for them to visit the workplaces and obtain from employers a list of the compounds regularly used. The Washington State Department of Agriculture is also a good source of information on local pesticide practices but will not substitute for the exact information obtainable from the workplace. Valuable information on the toxicology of specific pesticides can be obtained from label and package inserts and from pesticide dealers and manufacturers.
- When clinicians decide to end their responsibility as medical monitors, they should notify employers in writing and allow enough time for employers to arrange for a replacement.

Confidentiality and Records

In occupational health practice, the clinician's goals and ethics are no different from those in other forms of medical practice except for the added responsibility to the employer. Their primary concern is the protection and maintenance of employees' health. According to the WAC 296-802-100, Employee Medical and Exposure Records, "*The requirements of this chapter don't affect any other legal and ethical obligations the employer has to keep employee medical information confidential.*" (See <http://www.lni.wa.gov/wisha/rules/accesstorecords/default.htm>.) The interpretation of this is that the clinician needs to obtain written authorization from the employee to disclose specific test results and any other personal medical information not necessary for the employer to meet regulatory obligations.

This is in keeping within the spirit of the HIPAA privacy rule of "minimum necessary" disclosure. The employer only needs to know whether the employee's cholinesterase test results mean that the employer needs to institute a work practices investigation or medical removal. Washington State law prohibits unauthorized disclosure of personal medical information. Therefore, it is required that employee's participating in the cholinesterase testing program provide written authorization for disclosure of test information to the employer. The employer, or representatives not directly involved in providing occupational health services is limited to only receiving the cholinesterase percent change from baseline and recommendations relating to occupational exposure. .

The clinician may maintain test result records for the employer. The employer's responsibility is to simply ensure, to the extent feasible, that medical information is maintained in a confidential manner and for the specified period of time by the designated health care provider.

WAC 296-802-500 authorizes WISHA to have prompt access to occupational health records. HIPAA permits this access without authorization, consent, or opportunity to agree or object. 45 CFR 164.512 (d) Standard: uses and disclosures for health oversight activities: "(1) A covered entity may disclose protected health information to a health oversight agency for oversight activities authorized by law, including audits; civil, **administrative**, or criminal **investigations; inspections**;...civil, administrative, or criminal proceedings or actions; **or other activities necessary for the appropriate oversight of**...(iii) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards..." (emphasis added) A "health oversight agency" is defined as "an agency or authority of the United States, **a State**...or a person or entity acting under grant of authority from...such public agency...that is authorized by law to oversee the health care system...**or government programs in which health information is necessary to determine eligibility or compliance**..."

Appendix A: Frequently asked questions

What is the cholinesterase monitoring program?

Cholinesterase monitoring is a surveillance program that follows agricultural employees who handle cholinesterase-inhibiting pesticides with the signal words “**Danger**” or “**Warning**” on the label. This is accomplished by periodically measuring cholinesterase activity levels and comparing the results to previously established baseline activity levels measured prior to exposure to these pesticides. These steps may include a review of the work practices, safety equipment, and employee pesticide handling practices, and for more severe inhibition, temporary removal of the employee from exposure.

Which employees are monitored?

Agricultural employees who “handle” toxicity Category I or II organophosphate (OP) or N-methyl-carbamate pesticides with the signal words “**Danger**” or “**Warning**” are monitored. Handlers include mixers, loaders, applicators (both ground and aerial application), and flaggers.

Employees whose sole exposure is limited to handling N-methyl-carbamates are not required to undergo cholinesterase testing. But time spent handling N-methyl carbamates is counted toward the 30 hour per 30-day threshold if class I or II OP’s are also handled.

Must employees participate in medical monitoring?

Yes, employees who may meet the exposure threshold must participate in medical monitoring by reporting for an initial clinic visit and discussing the risks and benefits of cholinesterase testing with the clinician at a minimum. At that time the employee may choose to participate in the cholinesterase testing program or decline to participate. The employee must sign a participation or declination statement.

How do we monitor the employee with multiple employers?

An employee may handle cholinesterase-inhibiting pesticides for more than one employer. During the initial visit and whenever cholinesterase depression is detected the clinician may want to ask employees if they handle pesticides for another employer. Baseline test results are portable and a current baseline done through one clinician or for one employer may be used by another. Follow your current procedures for transfer of medical information.

Hours spent handling OP and N-methyl-carbamate pesticides are tracked by the employer only for that time the employee handled for that employer. Neither the clinician nor employers are required to document aggregate time an employee spends handling for multiple employers. The rule requires that occupational health recommendations are to be provided to the employer that has sent the employee in for testing. When an employee’s cholinesterase level is depressed, it is recommended that the clinician inform the employee that work practices in all work places should be evaluated and that all exposure to cholinesterase-inhibiting pesticides should be avoided until cholinesterase levels return to within 20% of baseline.

What is the purpose of medical monitoring?

The purpose of medical monitoring is to prevent illness caused by exposure to OP and N-methyl-carbamate cholinesterase-inhibiting pesticides. By monitoring the employees’ cholinesterase levels, illness can be prevented if a significant lowering or inhibition of their cholinesterase activity levels can be detected early, and they are removed from further exposure to cholinesterase-inhibiting pesticides before symptoms occur. Monitoring employees already removed from work for depressed cholinesterase levels will help determine when it will be safe for them to return to that work. Other benefits of monitoring are forced vigilance, increased worker and employer awareness of how toxic these chemicals are, and development of a common goal of safe handling of highly toxic OP and N-methyl-carbamate pesticides.

Do other agricultural employees need medical monitoring?

If employees also mix, load, or apply toxicity category I or II OP and N-methyl-carbamate pesticides or are flaggers for 30 or more hours in any consecutive 30-day period then they will need medical monitoring. If the employees do not perform any of these tasks, then they do not need to be monitored because other means, suffice to prevent exposure, such as restricted entry intervals and pre-harvest intervals.

What are the pesticides with the signal words “Danger” and “Warning”

Pesticides labeled with the signal word “**Danger**” are in toxicity Category I and are highly and acutely toxic. Pesticides labeled with the signal word “**Warning**” are in toxicity Category II and are moderately acutely toxic. The employees requiring medical monitoring are those who handle organophosphate and N-methyl-carbamate pesticides, in these two more highly toxic categories, above predetermined exposure thresholds. Pesticides in Toxicity Categories III and IV are less toxic and are each labeled with the signal word “**Caution.**” (See Cholinesterase-inhibiting pesticide products at <http://agr.wa.gov/PestFert/Pesticides/EmployeeProtection.htm#ProductList>)

Who is responsible to provide medical monitoring?

The employer is responsible for contracting with a clinician to provide medical monitoring to qualifying employees. The employer must also maintain pesticide handling records for all employees handling covered pesticides. Handling hours must be reported for each periodic test to the clinician. The employer is required to ensure that copies of employee test results and the clinician’s written recommendations are maintained for seven years.

Who does the actual medical monitoring?

A physician or licensed health care professional contracted by the employer for this purpose does the actual medical monitoring. The employer is required to ensure that the clinician is familiar with the requirements of the rule, for example, by providing a copy of the rule or by confirming that the provider has attended training on cholinesterase monitoring. Only laboratories approved by L&I to provide cholinesterase testing services may be used.

How often are cholinesterase tests done?

The first tests are done to establish a baseline level in the employee prior to exposure to toxicity Categories I and II cholinesterase-inhibiting pesticides. Baseline tests should be done at least 30 days since last exposure to organophosphate or N-methyl-carbamate pesticides. Once the baseline is established, periodic tests should be done according to one of the following schedules:

- On a routine 30-day basis during the application season
- OR
- Within three days at the end of each qualifying period where the employee meets the exposure threshold

Results of the periodic follow-up tests must be interpreted as a percentage of the employee’s pre-exposure baseline level.

What tests are done?

Blood is drawn to measure the enzymes serum cholinesterase (also known as pseudo, serum, or butyrylcholinesterase) and red blood cell cholinesterase (also known as RBC, acetyl, or true cholinesterase).

Why are both the serum cholinesterase and the RBC cholinesterase measured?

Although RBC cholinesterase is the same enzyme that is found at the neuro-effector site and thought to reflect inactivation there more accurately, it is more difficult to measure and is depressed more slowly than serum cholinesterase. Some pesticides can preferentially lower the activity of either enzyme. For example, chlorpyrifos preferentially lower serum cholinesterase activity while phosmet and dimethoate preferentially lower RBC cholinesterase activity. Since each of these enzymes has different characteristics, measuring both will give a more accurate assessment of the cholinesterase activity level and, hence, any possible exposure.

Can a clinician require more frequent testing than what is required by the regulations?

Yes. Neither the *Guidelines* nor the regulations are intended to constrain the exercise of sound medical judgment. The rule sets forth the *minimum* requirements and does not restrict clinicians from providing more intensive supervision. It is clearly stated in the regulations that the employer must “*follow any additional occupational health recommendations from the physician or LHCP.*”

Can any laboratory do the cholinesterase tests?

No. Cholinesterase tests ordered by the medical supervisor for occupational health surveillance can only be done by laboratories approved by L&I. Right now the Washington State Department of Health Public Health Laboratory is the only laboratory approved to provide this service..

WA DOH Public Health Laboratory

1610 N.E. 150th Street

Shoreline, WA 98155-9701

Attention: Harold Ruark or Karin Kerr

Telephone: (206) 418-5400 • Fax: (206) 361-2904

<http://www.doh.wa.gov/EHSPHL/PHL/default.htm>.

How important is it to keep blood samples on ice?

Very important! Cholinesterase that is not fully “aged” in its inhibition with an organophosphate can reactivate spontaneously. In order to obtain accurate cholinesterase assay results, the blood samples must be cooled as soon as possible kept at 1° - 8°C after drawing and should be shipped in cold-pack containers to the laboratory. **Note: Full directions for shipping are on the reverse side of the test request form.**

Are there other factors of the testing procedure that can affect the test results?

Yes. One of these is the blood draw itself. The area from which the blood is drawn should be as clean as possible since even a small amount of pesticide contaminant can affect the results. Blood must be collected in one 5ml EDTA Tube and one 5ml or 7ml Red Top or Tiger Top tube. Specimens must be shipped by overnight mail, as testing must be done within 48 hours after collection. Full directions for collection and shipping are on the reverse side of the test request form. The assay method used can also affect the results. The Ellman technique for the assay is the approved testing methodology. The pesticide itself can preferentially affect one enzyme or the other. Other factors that can potentially affect the results are laboratory error, incorrect calculation of the percentage change from baseline, and poor record keeping and organization.

What is a baseline value?

The baseline is the serum cholinesterase and RBC cholinesterase determinations that are measured at least 30-days prior to an employee’s exposure to toxicity categories I and II cholinesterase-inhibiting pesticides.

How is the baseline value established?

All baseline tests should be taken when the employee has had no exposure to cholinesterase inhibitors for at least 30 days. If circumstances preclude the achievement of a 30-day exposure-free period, then a “working baseline” should be obtained after the longest practicable exposure-free period possible and a notation made in the medical record as to the date when the last exposure occurred. If subsequent tests show a rise in activity, this new higher level should be considered the new baseline. However, a 30-day exposure-free period from cholinesterase-inhibiting pesticides prior to obtaining the baseline tests is the best and preferred way to establish the most accurate baseline value.

Why is the baseline value important?

The baseline value is important because it is the level against which all subsequent post-exposure cholinesterase determinations are compared. Since the baseline value is determined before the employee is exposed and the periodic follow-up tests occur after exposure, it is assumed that any subsequent inhibition of the cholinesterase activity is due to exposure to these pesticides. All of the subsequent determinations must be interpreted as a percentage of the baseline value. If this percentage falls below certain thresholds, then certain actions are taken, including investigation of employee work and safety practices and equipment and removal of the employee from further exposure to these pesticides. Effective monitoring requires an accurate baseline.

Can a cholinesterase determination be compared to the laboratory normal levels instead of to a baseline value?

No. Laboratory “normal levels” can have a very wide range. If this wide range of cholinesterase activity levels were used instead of a baseline for comparison with the follow-up activity levels, it would be difficult, if not impossible, to determine if an individual’s cholinesterase activity levels were actually depressed. In addition, a significant number of people will have normal baseline values that fall outside of the laboratory normal range. Therefore, the most accurate comparison would be to their own baseline value that was determined prior to any exposure to cholinesterase-inhibiting pesticides.

What are the levels of cholinesterase inhibition that trigger actions to be taken and what are these actions?

Also, if an employee is removed from working with cholinesterase-inhibiting pesticides, when can this employee return to work with those pesticides?

After a baseline value is established, working season testing (periodic follow-up testing) is begun if the employee handles toxicity Category I or II cholinesterase-inhibiting pesticides for more than 30 hours or more in any consecutive 30-day period

If either the follow-up serum or RBC cholinesterase activity levels fall below 20% from baseline, 30% from RBC cholinesterase baseline, or 40% from serum cholinesterase baseline, the following actions are triggered:

< 20% from the RBC or serum cholinesterase baseline values: Employer shall investigate the work practices of employees, including employee sanitation, pesticide handling procedures, and equipment usage, and conduct a review of safety equipment and its condition. Employers shall maintain a written record of the findings, changes in equipment or procedures, and any recommendations made to the employee. Depression to this level is an indication for prompt retesting.

≤ 30% from RBC cholinesterase baseline value: Employer shall remove from exposure to cholinesterase-inhibiting pesticides employees whose RBC cholinesterase activity level falls below this level. Employees will not be allowed to return to work with these pesticides until their RBC cholinesterase and serum cholinesterase activity levels each returns to within 20% from baseline. Employers shall maintain written records of the date of removal and the date when the employee is returned to exposure.

≤ 40% from serum cholinesterase baseline value: Employer shall remove from exposure to cholinesterase-inhibiting pesticides employees whose serum cholinesterase level falls below this level. Employees will not be allowed to return to work with these pesticides until their serum cholinesterase and RBC cholinesterase activity levels each returns to within 20% from baseline. Employers shall maintain written records of the date of removal and the date when the employee is returned to exposure.

If employees cholinesterase activity levels are below the action levels, does it mean they cannot work at all?

No. Employees cannot work with cholinesterase-inhibiting pesticides until their cholinesterase activity levels (the RBC or serum cholinesterase or both) recovers to within 20% from the baseline values. Unless employees have other work restrictions, they can work modified duty and do any other available work for which they are qualified.

If the cholinesterase activity levels are elevated, do employees have to be removed from further exposure to cholinesterase-inhibiting pesticides?

No. An elevation in cholinesterase activity levels is not an adverse effect of exposure to cholinesterase-inhibiting pesticides. A depression in cholinesterase activity levels is an adverse biological response of exposure to cholinesterase-inhibiting pesticides and is what the medical monitoring program is designed to detect. However, an elevation of cholinesterase activity over what was previously thought to be a baseline may indicate that the baseline was obtained during an unidentified exposure to a cholinesterase inhibitor.

Are there any medical or physical conditions other than exposure to organophosphates or N-methyl-carbamates that can affect cholinesterase levels?

Yes. Three per cent of the Anglo population has a genetically determined lower level of serum cholinesterase. As serum cholinesterase is the enzyme responsible for the metabolism of succinylcholine, these individuals have an increased susceptibility to this paralytic agent. There is no strong evidence indicating that these same individuals are more susceptible to organophosphates. This polymorphism does not affect RBC cholinesterase and these individuals should have normal activity levels of RBC cholinesterase. Serum cholinesterase can also be lowered by liver disease, malnutrition, alcoholism, nephrotic syndrome, early pregnancy, cocaine, carbon disulfide, organic mercury, birth control pills, and metaclopramide.

RBC cholinesterase levels can be affected by hemolytic anemia, pernicious anemia, recovery from hemorrhage, and conditions associated with reticulocytosis.

Four cholinesterase-inhibiting drugs currently are approved by the U.S. Food and Drug Administration to treat people who have been diagnosed with Alzheimer's disease (AD). The medications are: Reminyl® (galantamine), Exelon® (rivastigmine), Aricept® (donepezil), and Cognex® (tacrine).

Why does a clinician have to interpret the results? Can't the lab or the employer by themselves look at the results themselves and determine if any action has to be taken?

On the surface, it appears as if it would not be difficult for the laboratory or an employer to interpret the test results. In reality, it is not so simple and requires a clinician to make the proper interpretation. A clinician has the clinical training, background, and experience to understand how other conditions can affect test results and how to put those factors in their proper context to arrive at the proper interpretation of the results. In addition, determining if an employee can work or not and how often to retest are clinical decisions. Furthermore, a clinician supervisor is required by the regulations.

What is the aim of this publication?

The main purpose of this document is to describe the steps to be taken to provide a program for medical monitoring of employees who regularly handle toxicity Categories I and II cholinesterase-inhibiting pesticides. The regulations cited in these Guidelines set forth the minimum state requirements and are not intended to constrain clinicians from exercising sound medical judgment or from providing more intensive medical supervision. These Guidelines also briefly mention certain aspects of prophylaxis, treatment of organophosphate and N-methyl-carbamate poisoning, and the requirement of clinicians to report all cases of pesticide poisoning to the Department of Health.

Who maintains the records for the medical monitoring program and for how long do these records have to be maintained?

The rule requires the employer to keep a record of the physician or clinician providing medical supervision, pesticide-handling records, recommendations received from the medical supervisor, any signed declination forms, and cholinesterase test results. It is required that these records be maintained for seven years and that they be accessible to the employee and their designated representative. Cholinesterase tests results may be maintained by the clinician on behalf of the employer.

If an employee has been made ill by pesticides at work, is the employee expected to see the clinician providing cholinesterase-monitoring services for diagnosis and treatment?

Not necessarily, the clinician with whom the employer has the agreement is only contracted to provide cholinesterase monitoring as set forth in WAC 296-307-148 and described in these Guidelines. Under this agreement, the medical supervisor is not required to provide emergency or other medical treatment. The medical monitor, the employer, and the employee can have other arrangements and agreements to provide diagnosis and treatment for occupational or other illnesses or injuries, in which case, the designated clinician would see this worker.

Are pesticide related illnesses reportable?

Yes. A clinician who knows or believes that a patient is suffering from a pesticide poisoning or any disease or condition caused by a pesticide shall promptly report that fact to the Washington Poison Center by telephone within 24 hours (1-800-222-1222). Poisoning from all pesticides, including the cholinesterase inhibitors, is reportable. Definitely diagnosed cases as well as suspected but not definitely diagnosed cases are reportable.

<http://www.doh.wa.gov/ehp/ts/PEST.HTM>

If an employee is removed from exposure because their cholinesterase activity levels are 30% or more from the RBC cholinesterase baseline or 40% or more from the serum cholinesterase baseline, does this have to be reported?

If the removed worker is asymptomatic then this does not have to be reported to DOH. If the employee is ill with signs and symptoms consistent with or suspected to be a pesticide related illness (any pesticide including cholinesterase inhibiting ones), then this should be reported (See WAC 246-101-001 Notifiable Conditions).

Is there anything else the clinician, the employer, and the employee can do to implement and make the medical supervision program more effective?

It is strongly recommended that the clinician provide medical exams for each employee to be sure they are fit for the expected duties, be familiar with the pesticides used by the employers, and know the signs and symptoms caused by exposure to these pesticides.

It would be desirable for the employer to inform the clinician of the pesticides used in their operation, to explain medical monitoring to the employee, and to inform the clinician of the reason an employee was being seen. The employer is also required to provide employee training; to send in employee's for initial medical monitoring, baseline determinations and periodic testing; and to honor clinicians' recommendations and requests.

It would be desirable for the employee to present for baseline and working season testing, inform the employer of other exposures and of illness symptoms, and to follow the instructions of the clinician and the employer.

Is there any penalty for not following this rule correctly?

Clinicians are not responsible for ensuring employer and employee compliance with the rule. Employer citations for non-compliance with the rule will be determined in accordance with RCW 49.17 and WAC 296-800-350.

Appendix B. Sample Recommendation Form

Cholinesterase Monitoring HEALTH CARE PROVIDER RECOMMENDATIONS

Employer _____ Job Site _____

Employee _____ Test Date _____

This letter gives you the results of the above named employee's cholinesterase test and tells you what needs to be done based on the test result. Please contact me if you have any questions.

Cholinesterase level percent (%) change based on comparison to baseline:

Red blood cell _____ Serum _____

Occupational health recommendations:

- No action required. This is either notification of ___ normal baseline test results or ___ the employee's cholinesterase levels have not decreased more than 20% from baseline.
- The percent decrease for either RBC or serum cholinesterase is more than 20%. This probably means this employee had some exposure to cholinesterase-inhibiting pesticides. You must evaluate this employee's pesticide handling practices to try and identify possible exposure causes and make any necessary corrections.
- The percent decrease is 30% or more for RBC cholinesterase or 40% or more for serum cholinesterase. Remove the employee from handling and other potential exposure to cholinesterase-inhibiting pesticides until the employee's cholinesterase levels return to within 20% of baseline. Evaluate the employee's pesticide handling practices to identify possible exposure causes and make any necessary corrections. See #5 for directions on follow-up testing.
- These are the results of a test taken after removal from handling cholinesterase-inhibiting pesticides.
 - The employee's cholinesterase level(s) have not returned to within 20% of baseline. The employee may not return to handling cholinesterase-inhibiting pesticides or other duties with potential exposure. See #5 for directions on follow-up testing.
 - The employee's cholinesterase level(s) have returned to within 20% of baseline. The employee may return to work handling cholinesterase-inhibiting pesticides
- Other recommendations (specify):

The information contained on this form was telephoned provided verbally to the above named employer on
Date _____

Provider's Typed or Printed Name

Provider's Signature

Date

Answers to questions about cholinesterase test results

Why aren't my specific test results included in the Health Care Provider Recommendations?

Your employer only needs to know the percent change in your cholinesterase levels to make sure that you are being protected. Unless you have given the medical provider permission to share you test results with your employer they will not be included with the Recommendation. You may get your results by asking your employer to have the medical provider give them to you or by directly contacting the medical provider.

What does my baseline test result mean?

Your baseline test tells the medical provider what your personal cholinesterase levels are. Everybody has his or her own usual cholinesterase levels and the baseline result generally does not say anything about your health. The medical provider will compare tests that are taken after you have handled pesticides that affect cholinesterase to your baseline test in order see if you may have been over exposed.

What does a more than 20% drop in cholinesterase mean?

While cholinesterase levels do change a little from day to day it is unlikely that they would drop as much as 20 percent on their own. If either your red blood cell or serum cholinesterase levels drop by more than 20 percent from your baseline it is likely that you have been overexposed. You should not feel sick but your employer is required to make sure that you are handling pesticides safely so that you do not continue to be overexposed.

Why am I being removed from handling pesticides that affect cholinesterase?

Either your red blood cell cholinesterase has dropped 30 percent or more or your serum cholinesterase has dropped 40 percent or more. You should not feel sick but if you continue to be exposed you could get sick. Your body makes its own cholinesterase so your cholinesterase levels will come back on their own after you stop temporarily handling these pesticides. You may go back to handling when your cholinesterase levels return to within 20 percent of your baseline. In the meantime your employer will make sure that you are handling pesticides safely so that you do not continue to be overexposed.

While you are not handling these pesticides your employer must keep you in your job and pay you the same wages that you would have earned if you were handling pesticides.

What if my cholinesterase levels go up?

This usually does not mean anything. Cholinesterase levels move up and down a little from day to day.

What do I do if I feel sick after handling pesticides?

Tell your employer. Your employer will make sure that you receive a medical evaluation. You may be seen by the medical provider who is monitoring your cholinesterase levels or another provider such as the hospital emergency room. If are seen in the emergency room or somewhere else remember to tell them that you are in the state cholinesterase monitoring program.

If you have any additional questions please ask your employer or call

Medical Provider

Telephone

Appendix C. Sample Informed Consent or Declination Form

Mail completed form(s) and documentation to:
Department of Labor and Industries
PO Box 44610
Olympia WA 98504-4610



CHOLINESTERASE BLOOD TESTING CHOICE

FORM TO SAY “YES’ OR “NO” TO CHOLINESTERASE BLOOD TESTING

Please ask about anything on this form that you do not understand before deciding to have or not to have the cholinesterase blood tests

You are here because you handle organophosphate and N-methyl-carbamate pesticides with the words “DANGER” or “WARNING” on the label. Washington state safety rules give you the choice to have your blood cholinesterase tested or not.

Cholinesterase helps to control your body’s nervous system. Overexposure to organophosphate and N-methyl-carbamate pesticides can lower your cholinesterase and you can become sick.

Only you can decide to have the blood tests or not. It is against the law for your employer to interfere with your decision. After reading this form completely, sign your name in the space saying if you will or will not get the blood tests.

WHAT HAPPENS AND WHY

To get these blood tests, you must get a test when you have not handled these pesticides for a while (baseline). About 30 days after you start handling organophosphate and N-methyl-carbamate pesticides, you may get another test (follow-up). How often you are tested depends on how many hours you handle these pesticides in each 30 day period.

- The purpose of these tests is to detect overexposure and help prevent pesticide illness.
- Your employer must make sure that you can get the blood tests when tests are required but only if you choose to have blood tests.
- You pay nothing for the blood tests.
- Your employer will pay for all costs.

Every time you get the blood test a medical worker will take about 2 tablespoons of blood from a vein in your arm. This blood will go into two small tubes. The medical worker will use a sterile needle to take the blood. This part takes about 5 minutes. Then you will wear a Band-Aid on your arm for a few hours.

TEST RESULTS

Your follow-up test results could show that you have had too much pesticide exposure. Or, they could show that you are fine and you can continue to work as usual. You and your employer will be told what the recommendations from the test results are. If your cholinesterase level has dropped greatly you may need to stop handling organophosphate and N-methyl-carbamate pesticides until your cholinesterase returns to its usual level (baseline). Blood tests can show when it is safe for you to return to handling these pesticides. **The rule protects your job if you are temporarily removed from handling organophosphate and N-methyl-carbamate pesticides.**

The Department of Health and the Department of Labor and Industries in Washington State will also get the test results.

RISKS

The pain of a needlestick
You might get a bruise
You could feel a little dizzy
Rarely, someone gets an infection

BENEFITS

Tell if your pesticide handling practices and equipment are protecting you
Tell if you have had too much exposure to these pesticides
Avoid sickness from overexposure
Help you and your employer make the workplace safer

CHOLINESTERASE BLOOD TESTING CHOICE

INITIALS

YES, YES, I CHOOSE TO GET THE BLOOD TESTS

I have read this form (or had it read to me) and talked about the blood tests with the medical worker.

I CHOOSE TO GET THE CHOLINESTERASE BLOOD TESTS.

I also agree to allow (provider)

AND/OR the Department of Labor & Industries to share my cholinesterase test results with my employer

 for a period not longer than 1 year from the signature date.

Date	Printed Name	Patient Signature
------	--------------	-------------------

Date	Printed Name	Witness Signature
------	--------------	-------------------

INITIALS

NO, I CHOOSE NOT TO GET THE BLOOD TESTS

I have read this form (or had it read to me) and talked about the blood tests with the medical worker. I understand the risks and benefits of cholinesterase testing and CHOOSE NOT TO GET THE CHOLINESTERASE BLOOD TESTS. I also understand that I can change my mind at any time and get the blood tests without cost.

Date	Printed Name	Patient Signature
------	--------------	-------------------

Date	Printed Name	Witness Signature
------	--------------	-------------------

Complete this section only if form is read to participant

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant. The participant freely consented to participate in the screening program.

Date	Printed Name	Witness Signature
------	--------------	-------------------

Appendix D. Sample medical monitor agreement form

SAMPLE FORM LETTER AND AGREEMENT

Dear Mr./Ms. _____ Address: _____

This letter is in response to your request that I provide medical supervision to those of your employees requiring such supervision, as described in the L&I Cholinesterase Monitoring Rule (WAC 296-307-148).

In agreeing to provide medical monitoring, I expect your agreement to abide by the provisions of the Cholinesterase Monitoring Rule and I intend to perform my functions in accordance with the specified *Guidelines* provided by L&I.

The employees covered by this regulation are employees who handle organophosphate and N-methyl-carbamate pesticides with the signal word "DANGER" or "WARNING" on the label. Employees who handle these pesticides for 30 or more hours in any consecutive 30-day period require medical monitoring.

It is your responsibility to have that employee come to me for an initial evaluation. A record of handling hours should accompany each employee at the time of testing. If the employee agrees to participate in the cholinesterase-testing program it is your responsibility to send the employee for periodic cholinesterase testing. Employees will be required to have their baseline retested, or verified, every year.

According to the Rule, the employer shall ensure that periodic cholinesterase testing is conducted at least every 30 days that the employee meets the testing exposure threshold and at least as frequently as recommended by the medical supervisor. I may schedule more frequent tests as necessary, according to the test results.

With mutual cooperation we should be able to assure your employees a safe work situation.

(Signature)

(Date)

(Address)

(Telephone)

Appendix E. Initiation of medical monitoring

INITIATION OF MEDICAL MONITORING

NOTIFICATION BY EMPLOYER TO PHYSICIAN
REGARDING NEW EMPLOYEE TO BE MONITORED.

Employer_____

Address_____

Employee_____ Job Title_____

Employee date of birth_____

Address and Phone_____

To (clinic or health care provider)_____

The above named employee will begin handling organophosphate or N-methyl-carbamate pesticides, beginning on (approximate date)_____.

Payment to you for clinical services is guaranteed.

(Employer Signature)

(Date)

Appendix F. Employee no longer requires medical monitoring

**NOTIFICATION THAT EMPLOYEE NO LONGER REQUIRES
MEDICAL SUPERVISION**

To (Clinic or health care provider) _____

Employee name _____

Employee date of birth _____

The above named employee is no longer employed by me [] or is no longer involved in regularly handling organophosphate or N-methyl-carbamate pesticides with the signal words “DANGER” or “WARNING” [].

Employer _____

Signed by _____

Title _____

Date effective _____

Appendix G. Cholinesterase monitoring information

CHOLINESTERASE MONITORING INFORMATION

Type of work*	Pesticides used**	Exposure threshold
Mixing, loading, and application, handling open containers, disposing of pesticides, maintaining contaminated equipment	Organophosphates and N-methyl-carbamates with the word "DANGER" or "WARNING" on label (Category I or II).	30 or more hours in any consecutive 30-day period.

* See definition of "handler: in WAC 296-307-11005

** See WSDA Pesticide Web site for a list of covered pesticides

<http://agr.wa.gov/PestFert/Pesticides/WorkerProtection.htm>

REQUIRED FREQUENCY OF BLOOD CHOLINESTERASE TESTING

Employee who meet	Frequency of testing
New Employee	Establish employee participation. Baseline testing 30-days after employee last handled cholinesterase-inhibiting pesticides.*
Periodic testing	Test once in every 30-day period or whenever the exposure threshold is met (but no more often than every 30 days).**
Follow-up testing	Retesting after significant RBC cholinesterase depression should be scheduled based on a 1%/day regeneration rate. Initial retesting after significant serum cholinesterase depression may be conducted within 24 hours then weekly thereafter

*Employees whose exposure is limited to-N-methyl-carbamates are exempt from baseline and periodic test requirements.

**Hours spent mixing and loading using closed systems (e.g. water-soluble packets) are not counted in the determination for periodic testing.

Appendix H.

WASHINGTON STATE DEPARTMENT OF HEALTH
 PUBLIC HEALTH LABORATORIES
 1610 NE 150th St., Shoreline, WA 98155-9701
 (206) 418-5501

Please print clearly. Missing information may delay test order processing.

NOTE: Upon receipt of specimen, lab will assume that clinician has completed informed consent process with farm worker.

<p>A. FARM WORKER NAME: Last _____ First: _____ Middle _____</p> <p>B. DATE OF BIRTH (mm/dd/yyyy): ____/____/____</p> <p>C. GENDER: <input type="checkbox"/> Male <input type="checkbox"/> Female</p> <p>D. ETHNICITY: <input type="checkbox"/> Latino/Hispanic <input type="checkbox"/> Not Latino/Hispanic</p>	<p>I. EMPLOYER: Company _____</p> <p>Contact: Last _____ First _____ Tel: (_____) _____ - _____ ext. _____</p> <p>J. EMPLOYER ADDRESS: Street / P.O. Box _____ City _____ State: _____ Zip: _____</p>
<p>E. MOTHER'S MAIDEN NAME: Last _____ First _____</p>	<p>K. MONITORING STAGE:</p> <p style="padding-left: 20px;">Baseline Test</p> <p style="padding-left: 40px;"><input type="checkbox"/> Exposure-free in the prior 30 days</p> <p style="padding-left: 40px;"><input type="checkbox"/> Not exposure-free in the prior 30 days "<i>working baseline</i>"</p> <p style="padding-left: 20px;">Follow-Up/Periodic Test</p> <p style="padding-left: 40px;"><input type="checkbox"/> Follow Up/ Periodic (<i>Cholinesterase Monitoring Handling Hours Report Form must be attached</i>)</p>
<p>F. CLINICIAN ORDERING TEST: Last : _____ First _____</p> <p>G. PHONE AND FAX NUMBERS FOR RECEIVING RESULTS: Tel: (_____) _____ - _____ ext. _____ AND Fax: (_____) _____ - _____ ext. _____</p> <p>H. CLINIC INFORMATION: Name _____ Street / P.O. Box: _____ City: _____ State: WA Zip: _____ Tel: (_____) _____ - _____ Ext. _____</p>	<p>INFORMATION ABOUT SPECIMEN DRAW (to be completed at time of draw):</p> <p>L. DATE/ TIME SPECIMEN DRAWN: Date ____/____/____ Time: ____ : ____ am / pm (circle one)</p> <p>M. PHLEBOTOMIST NAME: Last _____ First _____</p>

FOR LABORATORY USE ONLY - Do not write below this line

LAB ACCESSION NUMBER:	DATE RECEIVED:	METHOD: Ellman Method/ Auto Analyzer / Roche Reagent	REPORT DATE:
<p>RBC ChE: _____ μMol/min/gHb SUPERVISOR: _____</p> <p>RBC Reference Range: 8.5 – 16.0 μMol/min/gHb</p> <p>DATE ANALYZED: ____/____/____ TIME ANALYZED: ____ : ____ am / pm ANALYST: _____</p> <p>Serum ChE: _____ μMol/min/mL</p> <p>Serum Reference Range: 3.0 – 6.5 μMol/min/mL</p> <p>DATE ANALYZED: ____/____/____ TIME ANALYZED: ____ : ____ am / pm ANALYST: _____</p>		<p>NOTES:</p> <p>Temperature when received at lab: _____ ° C</p>	

Appendix I: Instructions for collecting and Shipping Blood

COLLECTION

1. Blood should be collected only by trained personnel using aseptic methods and working under the direction of a qualified, licensed practitioner.
2. **Use only plastic vacutainer tubes to avoid breakage.** Please contact the WA DOH Public Health Laboratories (PHL) at (206) 418-5494 if you do not have recommended tubes at your facility.
3. For each patient:
 - Collect 5 ml of whole blood into EDTA tube (Lavender top, # BD-367-863).
 - Collect an additional 5 or 7 ml of whole blood into Red top or Red/Gray "Tiger Stripe" tube (#BD-367-986).
 - Use 21 gauge needle to minimize mechanical damage of red blood cells (RBC).
 - If patient is sent to the Phlebotomist directly from the area of pesticide application, thoroughly swab the area of venipuncture to preclude contamination of the blood specimen with possible skin-surface pesticide.
 - Label each tube with the patient's full name.
 - Fill out the Cholinesterase (ChE) Test Request Form with as much patient information as possible. Correct and complete specimen identification is essential for data integrity. **For follow up/periodic testing, attach Cholinesterase Monitoring Handling Hours Report Form to test request form.**
4. The blood collected in Red Top or Tiger Stripe tube is used for preparation of serum specimen. It is important for the integrity of ChE results to separate serum from red blood cells as soon as possible after blood collection to minimize hemolysis of red blood cells. If your clinic has a centrifuge to spin down blood, you can use either the Red Top or Tiger Stripe tube for blood collection. Make sure that blood is properly clotted (wait 15-30 minutes if needed), then spin it down at 3,000 RPM for 10 minutes and draw serum off into a plastic or plastic coated glass tube for shipment. If your clinic does **not** have a centrifuge, you should use **only** the Tiger Stripe tube for collecting blood for serum specimen. This tube contains a clot separator assembly that minimizes hemolysis during the specimen transportation.
5. Gently rock the EDTA (Lavender top) tube for about 45 seconds to fully mix the whole blood and EDTA.
6. Prepared whole blood specimen (Lavender top tube) and serum specimen must be refrigerated at 1° C to 4° C until they are cold-packed for shipping to PHL.

NOTE: Specimens are to be collected on Sundays through Thursdays. DO NOT collect specimens on Fridays or Saturdays. The laboratory will not be performing cholinesterase testing on Saturdays or Sundays.

SHIPPING

1. **Specimens must be tested within 48 hours after the time of collection in order to maintain analytical integrity for this assay. Therefore, specimens must be shipped and received by PHL within 24 hours of collection.**
2. Pack properly identified serum and whole blood samples with enough ice gel packing to keep specimens at 1° C to 8° C (34 – 46° F) for 24 hours. Use Diagnostic Shipping System package provided by Thermal Isolating Systems (ThermoSafe) to ship 8-16 tubes. This package consists of a mailer for shipping 8 tubes, an insulated container, with inside dimensions of 11" x 8" x 8", and one or two pound gel packs. This system should keep specimens of blood within the desired temperature of 1° C to 8° C for 24 hours.
3. Place a tube filled with water into the package so the temperature inside a shipping package can be measured upon arrival at PHL.
4. Secure specimens tightly in the mailer to avoid unnecessary motion of the tubes since hemolysis in transit is problematic for the cholinesterase procedure.
5. Ship specimens with courier or mail carrier with guaranteed NEXT DAY delivery to: **WA DOH Public Health Laboratory, 1610 N.E. 150th Street, Shoreline, WA 98155-9701, attention Harold Ruark or Karin Kerr.**

CRITERIA FOR SPECIMEN REJECTION

1. Specimen tube is glass, is different size than specified, or is broken or leaking.
2. Specimen is not delivered to PHL within 24 - 36 hours from time of collection.
3. Specimen arrives at PHL at temperature higher than 10° C.
4. Specimen is hemolyzed.
5. Minimum patient identification not provided.

For questions about ChE specimen collection and shipment, call **Connie Abad** (206) 418-5501 or **Marina Silverstone** (206) 418-5494.

For assistance contact:
 Department of Labor and Industries
 (360) 902-5478
 e-mail toug235@Lni.wa.gov



CHOLINESTERASE MONITORING HANDLING HOURS REPORT

Instructions: Per RCW 49.17.285

- **Employers** -- complete the handling hours report for the employee for each periodic/follow-up test. Provided this report to your health care provider.
- **Health care providers** -- submit the completed form to the Public Health Laboratory, attached to the Lab slip for the test.
- Make sure the employee's worksite information is completed.

Handling hours report

Employee name (Last, First, MI)	Date of birth	Date of test	Hrs 30 days before testing	Total hrs year to date	Test accession # Lab use only

Employee worksite information

Worksite		
Worksite Address		
City	State	ZIP+4
Company Name		
Contact Name	Telephone number	FAX number

Provider Information

Clinic/Provider	Provider ID
Contact Name	Telephone number FAX number

Appendix K: Chapter 296-307-148 WAC, Cholinesterase Monitoring

See The WISHA Cholinesterase Monitoring Web page at

<http://www.lni.wa.gov/WISHA/Rules/agriculture/HTML/part-j-1.htm>